(d) Where to file: all communications pursuant to this subpart shall be addressed to the attention of the product jurisdiction officer. Such a request, in its mailing cover should be plainly marked ''Request for Designation.'' Concurrent submissions of electronic copies of Requests for Designation may be addressed to *combination@fda.gov*.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 37077, June 23, 2003]

§ 3.8 Letter of designation.

(a) Each request for designation will be reviewed for completeness within 5 working days of receipt. Any request for designation determined to be incomplete will be returned to the applicant with a request for the missing information. The sponsor of an accepted request for designation will be notified of the filing date.

(b) Within 60 days of the filing date of a request for designation, the product jurisdiction officer will issue a letter of designation to the sponsor, with copies to the centers, specifying the agency component designated to have primary jurisdiction for the premarket review and regulation of the product at issue, and any consulting agency components. The product jurisdiction officer may request a meeting with the sponsor during the review period to discuss the request for designation. If the product jurisdiction officer has not issued a letter of designation within 60 days of the filing date of a request for designation, the sponsor's recommendation of the center with primary jurisdiction, in accordance with §3.7(c)(3), shall become the designated agency component.

(c) Request for reconsideration by sponsor: If the sponsor disagrees with the designation, it may request the product jurisdiction officer to reconsider the decision by filing, within 15 days of receipt of the letter of designation, a written request for reconsideration not exceeding 5 pages. No new information may be included in a request for reconsideration. The product jurisdiction officer shall review and act on the request in writing within 15 days of its receipt.

§ 3.9 Effect of letter of designation.

(a) The letter of designation constitutes an agency determination that is subject to change only as provided in paragraph (b) of this section.

(b) The product jurisdiction officer may change the designated agency component with the written consent of the sponsor, or without its consent to protect the public health or for other compelling reasons. A sponsor shall be given 30 days written notice of any proposed nonconsensual change in designated agency component. The sponsor may request an additional 30 days to submit written objections, not to exceed 15 pages, to the proposed change, and shall be granted, upon request, a timely meeting with the product jurisdiction officer and appropriate center officials. Within 30 days of receipt of the sponsor's written objections, the product jurisdiction officer shall issue to the sponsor, with copies to appropriate center officials, a written determination setting forth a statement of reasons for the proposed change in designated agency component. A nonconsensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner.

[56 FR 58756, Nov. 21, 1991, as amended at 68 FR 37077, June 23, 2003]

§ 3.10 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application for marketing approval or required investigational notice during the pendency of the review by the product jurisdiction officer.

Subpart B [Reserved]

PART 5—ORGANIZATION

Subparts A–L [Reserved]

Subpart M—Organization

Sec.

AUTHORITY: 5 U.S.C. 552; 21 U.S.C. 301–397.

SOURCE: 69 FR 17286, Apr. 2, 2004, unless otherwise noted.

Subparts A–L [Reserved]

Subpart M—Organization

§ 5.1100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.[1]

Office of the Chief Counsel.[2]

Office of Equal Employment Opportunity and Diversity.

Office of the Administrative Law Judge.

Office of External Relations.

Office of Executive Secretariat.

Office of Public Affairs.

Office of the Ombudsman.

Office of Special Health Issues.

Office of Policy and Planning.

Office of Policy.

Office of Planning.

Office of Management.

Office of the Chief Information Officer.

Office of Financial Management.

Office of Shared Services.[3]

Office of Management Programs.

Office of Executive Operations.

Office of Science and Health Coordination.

Office of Orphan Products Development.

Office of Women's Health.

Office of International Activities and Strategic Initiatives.

Office of International Programs.

Office of Pediatric Therapeutics.

Office of Combination Products.

Office of Legislation.

Office of Crisis Management.

Office of Emergency Operations.

Office of Security Operations, Policy and Planning.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH[4]

Office of the Center Director.

Scientific Advisors and Consultants Staff.

Equal Employment Opportunity and Workforce Diversity Staff.

Quality Assurance Staff.

Regulations and Policy Staff.

Veterinary Services Staff.

Office of Management.

Regulatory Information Management Staff.

Division of Planning, Evaluation, and Budget.

Division of Management Services.

Office of Compliance and Biologics Quality.

Division of Case Management.

Division of Manufacturing and Product Quality.

Division of Inspections and Surveillance.

Office of Blood Research and Review.

Policy and Publications Staff.

Division of Emerging and Transfusion Transmitted Diseases.

Division of Hematology.

Division of Blood Applications.

Office of Vaccines Research and Review.

Analytical Chemistry Staff.

Standards and Testing Staff.

Division of Bacterial, Parasitic, and Allergenic Products.

Division of Viral Products.

Division of Vaccines and Related Products Applications.

Office of Communication, Training, and Manufacturers Assistance.

Division of Disclosure and Oversight Management.

Division of Manufacturers Assistance and Training.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

[2] The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

[3] Mailing address: 5630 Fishers Lane, Rockville, MD 20852.

[4] Mailing address: 1401 Rockville Pike, Rockville, MD 20852–1448.

Division of Communication and Consumer Affairs.

Office of Biostatistics and Epidemiology.

Division of Biostatistics.

Division of Epidemiology.

Office of Information Management.

Division of Information Operations.

Division of Information Development.

Office of Cellular, Tissue, and Gene Therapies.

Division of Cell and Gene Therapies.

Division of Clinical Evaluation and Pharmacology/Toxicology Review.

Division of Human Tissues.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION[5]

Office of the Center Director.

Food Safety Staff.

Office of Science.

Quality Assurance Staff.

CFSAN Staff College.

Microbial Research and Risk Assessment Staff.

JIFSAN Liaison Staff.

CFSAN Food Advisory Committee Staff.

Office of Applied Research and Safety Assessment.

Muirkirk Technical Operations Staff.

Division of Molecular Biology.

Division of Virulence Assessment.

Division of Toxicology.

Office of Regulations and Policy.

Regulations Management Staff.

Office of Constituent Operations.

Consumer Education Staff.

International Activities Staff.

Industry Activities Staff.

Office of Management Systems.

Safety Management Staff.

Division of Information Resources Management.

Division of Planning and Financial Resources Management.

Division of Program Support Services.

Office of Operations.

Equal Employment Opportunity Staff.

Executive Operations Staff.

Office of Cosmetics and Colors.

Division of Color Certification and Technology.

Division of Cosmetics and Compliance.

Office of Nutritional Products, Labeling and Dietary Supplements.

Infant Formula and Medical Foods Staff.

Division of Dietary Supplement Programs and Compliance.

Division of Food Labeling, Standards and Compliance.

Division of Nutrition Programs and Labeling.

Division of Research and Applied Technology.

Office of Food Additive Safety.

Division of Petition Review.

Division of Chemistry Research and Environmental Review.

Division of Food Contact Notifications.

Division of Biotechnology and GRAS Notice Review.

Office of Plant and Dairy Foods and Beverages.

Division of Pesticides and Industrial Chemicals.

Division of Natural Products.

Division of Food Processing and Packaging.

Division of Plant Product Safety.

Division of Dairy and Egg Safety.

Division of Risk Assessment.

Division of Microbiological Studies.

Office of Seafood.

Division of Programs and Enforcement Policy.

Division of Science and Applied Technology.

Office of Compliance.

Emergency Coordination and Response Staff.

Division of Enforcement.

Division of Field Programs.

Division of Cooperative Programs.

Office of Scientific Analysis and Support.

CFSAN Adverse Events Reporting System Staff.

Division of General Scientific Support.

Division of Mathematics.

Division of Market Studies.

[5] Mailing address: 5100 Paint Branch Pkwy., College Park, MD 20740–3835.

CENTER FOR DRUG EVALUATION AND RESEARCH[1]

Office of the Center Director.

Equal Employment Opportunity Staff.

Controlled Substance Staff.

Office of Regulatory Policy.

Division of Regulatory Policy I.

Division of Regulatory Policy II.

Division of Information Disclosure Policy.

Office of Management.[1]

Division of Management and Budget.[1]

Division of Management Services.[1]

Office of Training and Communication.[1]

Division of Training and Development.

Division of Public Affairs.

Division of Drug Information.

Division of Library and Information Services.

Office of Compliance.[1]

Division of New Drugs and Labeling Compliance (HFD–310).

Division of Manufacturing and Product Quality (HFD–320).

Division of Compliance Risk Management and Surveillance (HFD–330).

Office of Information Technology.[1]

Quality Assurance Staff.

Technology Support Services Staff.

Division of Applications Development and Services.

Division of Infrastructure Management and Services.

Office of Medical Policy.[1]

Division of Drug Marketing, Advertising and Communication.[1]

Division of Scientific Investigations.[6]

Office of Pharmacoepidemiology and Statistical Science.

Office of Drug Safety.

Division of Surveillance, Research and Communication Support.

Division of Medication Errors and Technical Support.

Division of Drug Risk Evaluation.

Office of Biostatistics.

Quantitative Methods and Research Staff.

Division of Biometrics I.

Division of Biometrics II.

Division of Biometrics III.

Office of Executive Programs.

Executive Operations Staff.

Quality Assurance Staff.

Advisors and Consultants Staff.[2]

Office of Counter-Terrorism and Pediatric Drug Development.

Division of Counter-Terrorism.

Division of Pediatric Drug Development.

Office of Information Management.

Business Information Staff.

Review Technology Staff.

Division of Records Management.

Office of New Drugs.[1]

Office of Drug Evaluation I.[1]

Division of Cardio-Renal Drug Products.

Division of Neuropharmacological Drug Products.

Division of Oncology Drug Products.

Office of Drug Evaluation II.[1]

Division of Metabolic and Endocrine Drug Products.

Division of Pulmonary and Allergy Drug Products.

Division of Anesthetic, Critical Care and Addiction Drug Products.

Office of Drug Evaluation III.[1]

Division of Gastrointestinal and Coagulation Drug Products.

Division of Medical Imaging and Radiopharmaceutical Drug Products.

Division of Reproductive and Urologic Drug Products.

Office of Drug Evaluation IV. [1]

Division of Anti-Infective Drug Products.

Division of Anti-Viral Drug Products.

Division of Special Pathogen and Immunologic Drug Products.

Office of Drug Evaluation V.

Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products.

Division of Dermatologic and Dental Drug Products.

Division of Over-The-Counter Drug Products.

Office of Drug Evaluation VI.

[6] Mailing address: 7520 Standish Pl., Rockville, MD 20855.

Division of Therapeutic Biological Oncology Products.

Division of Therapeutic Biological Internal Medicine Products.

Division of Review Management and Policy.

Office of Pharmaceutical Science.[1]

Quality Implementation Staff.[1]

Operations Staff.[1]

Informatics and Computational Safety Analysis Staff.

Office of Clinical Pharmacology and Biopharmaceutics.

Pharmacometrics Staff.

Division of Pharmaceutical Evaluation I.[1]

Division of Pharmaceutical Evaluation II.[1]

Division of Pharmaceutical Evaluation III.[1]

Office of Generic Drugs.[6]

Division of Bioequivalence.

Division of Chemistry I.

Division of Chemistry II.

Division of Labeling and Program Support.

Division of Chemistry III.

Office of New Drug Chemistry.[1]

Division of New Drug Chemistry I.[1]

Division of New Drug Chemistry II.[1]

Division of New Drug Chemistry III.[1]

Office of Testing and Research.[1]

Laboratory of Clinical Pharmacology.[7]

Division of Applied Pharmacology Research.[8]

Division of Pharmaceutical Analysis.[9]

Division of Product Quality Research.[1]

Office of Biotechnology Products.

Division of Monoclonal Antibodies.

Division of Therapeutic Protein.

OFFICE OF REGULATORY AFFAIRS[1]

Equal Employment Opportunity Staff.

Office of Resource Management.

Strategic Initiatives Staff.

Division of Planning, Evaluation, and Management.

Division of Human Resource Development.

Division of Management Operations.

Division of Personnel Operations.

Office of Information Technology.

Office of Enforcement.

Division of Compliance Management and Operations.

Division of Compliance Policy.

Division of Compliance Information and Quality Assurance.

Office of Regional Operations.

Division of Federal-State Relations.

Division of Field Science.

Division of Import Operations and Policy.

Division of Field Investigations.

Office of Criminal Investigations.

Office of Internal Affairs.

Mid-Atlantic Area Office.[10]

Midwest Area Office.[11]

Northeast Area Office.[12]

Pacific Area Office.[13]

Southeast Area Office.[14]

Southwest Area Office.[15]

CENTER FOR VETERINARY MEDICINE[16]

Office of the Center Director.

Office of Management.

Management Services Staff.

Information Resources Management Staff.

Office of New Animal Drug Evaluation.

Division of Therapeutic Drugs for Food Animals.

Division of Biometrics and Production Drugs.

[7] Mailing address: Four Research Ct., Rockville, MD 20850.

[8] Mailing address: 8301 Muirkirk Rd., Laurel, MD 20708.

[9] Mailing address: 1114 Market St., St. Louis, MO 63101.

[10] Mailing address: 900 U.S. Customhouse, Second Chestnut St., Philadelphia, PA 19106.

[11] Mailing address: 901 Warrenville Rd., suite 360, Lisle, IL 60532.

[12] Mailing address: 850 Third Ave., Brooklyn, NY 11232.

[13] Mailing address: 13301 Clay St., Oakland, CA 94512.

[14] Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

[15] Mailing address: 7920 Elmbrook Rd., Dallas, TX 75247.

[16] Mailing address: 7500 Standish Pl., MPN–2, Rockville, MD 20855.

Division of Therapeutic Drugs for Non-Food Animals.
Division of Human Food Safety.
Division of Manufacturing Technologies.
Office of Surveillance and Compliance.
Division of Surveillance.
Division of Animal Feeds.
Division of Compliance.
Division of Epidemiology.
Office of Research.
Administrative Staff.
Division of Residue Chemistry.
Division of Animal Research.
Division of Animal and Food Microbiology.
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH[17]
Office of the Center Director.
Equal Employment Opportunity Staff.
Office of Systems and Management.
Division of Ethics and Management Operations.
Division of Information Technology.
Division of Planning, Analysis and Finance.
Office of Compliance.
Promotion and Advertising Policy Staff.
Division of Bioresearch Monitoring.
Division of Program Operations.
Division of Enforcement A.
Division of Enforcement B.
Office of Device Evaluation.
Program Management Staff.
Program Operations Staff.
Division of Cardiovascular Devices.
Division of Reproductive, Abdominal, and Radiological Devices.
Division of General, Restorative, and Neurological Devices.
Division of Ophthalmic, and Ear, Nose and Throat Devices.
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.
Office of Science and Technology.
Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences.
Division of Electronics and Computer Sciences.
Division of Management, Information and Support Services.
Office of Health and Industry Programs.
Program Operations Staff.
Regulations Staff.
Staff College.
Division of Device User Programs and Systems Analysis.
Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.
Office of Surveillance and Biometrics.
Issues Management Staff.
Division of Biostatistics.
Division of Postmarket Surveillance.
Division of Surveillance Systems.
Office of In Vitro Diagnostic Device Evaluation and Safety.
Division of Chemistry and Toxicology Devices.
Division of Immunology and Hematology Devices.
Division of Microbiology.
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH[18]
Office of the Center Director.
Environmental Health and Program Assurance Staff.
Office of Research.
Technology Advancement Staff.
Division of Biochemical Toxicology.
Division of Genetic and Reproductive Toxicology.
Division of Biometry and Risk Assessment.
Division of Microbiology.
Division of Chemistry.
Division of Neurotoxicology.
Division of Veterinary Services.
Division of Molecular Epidemiology.
Office of Management.
Office of Management Services.

[17] Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

[18] Mailing address: 3900 NCTR Dr., Jefferson, AR 72079.

Division of Facilities, Engineering and Maintenance.

Division of Administrative Services.

Division of Contracts and Acquisitions.

Office of Planning, Finance and Information Technology.

Division of Planning.

Division of Financial Management.

Division of Information Technology.

[69 FR 17286, Apr. 2, 2004, as amended at 69 FR 52600, Aug. 27, 2004]

§ 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is 5600 Fishers Lane, rm. 6–05, Rockville, MD 20857.[1]

§ 5.1110 FDA public information offices.

(a) *Division of Dockets Management (HFA–305)*. The Division of Dockets Management public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Telephone: 301–827–6860.

(b) *Division of Freedom of Information (HFI–35)*. The Freedom of Information public room is located in rm. 12A–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6567.

(c) *Press Relations Staff (HFI–40)*. Press offices are located in rm. 15–A07, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6242; and at 5100 Paint Branch Pkwy., College Park, MD 20740. Telephone: 301–436–2335.

§ 5.1115 Field structure.

NORTHEAST REGION

Regional Field Office: 158–15 Liberty Ave., Jamaica, NY 11433.

Northeast Regional Laboratory: 158–15 Liberty Ave., Jamaica, NY 11433.

New York District Office: 158–15 Liberty Ave., Jamaica, NY 11433.

New England District Office: One Montvale Ave., Stoneham, MA 02180.

Winchester Engineering and Analytical Center: 109 Holton St., Winchester, MA 01890.

CENTRAL REGION

Regional Field Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Philadelphia District Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Baltimore District Office: 6000 Metro Dr., suite 101, Baltimore, MD 21215.

Cincinnati District Office: 6751 Steger Dr., Cincinnati, OH 45237–3097.

Forensic Chemistry Center: 6751 Steger Dr., Cincinnati, OH 45237–3097.

New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d floor, Parsippany, NJ 07054.

Chicago District Office: 550 West Jackson Blvd., suite 1500, South Chicago, IL 60661.

Detroit District Office: 300 River Pl., suite 5900, Detroit, MI 48207.

Minneapolis District Office: 212 Third Ave. South, Minneapolis, MN 55401.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

New Orleans District Office: 6600 Plaza Dr., suite 400, New Orleans, LA 70122.

Florida District Office: 555 Winderley, suite 200, Maitland, FL 32751.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901–3223.

SOUTHWEST REGION

Regional Field Office: 4040 North Central Expressway, suite 900, Dallas, TX 75204.

Dallas District Office: 4040 North Central Expressway, suite 300, Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225–0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214–3338.

[1] The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

St. Louis Branch: 12 Sunnen Dr., suite 122, St. Louis, MO 63143–3800.

Arkansas Regional Laboratory: 3900 NCTR Rd., Bldg. 26, Jefferson, AR 72079–9502.

Southwest Import District Office: 4040 North Central Expressway, suite 300, Dallas, TX 75204.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180–N, Oakland, CA 94512–5217.

San Francisco District Office: 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070.

Los Angeles District Office: 19701 Fairchild, Irvine, CA 92612.

Seattle District Office: 22201 23rd Dr. SE., Bothell, WA 98021–4421.

Pacific Regional Laboratory, SW: 19701 Fairchild, Irvine, CA 92612.

Pacific Regional Laboratory, NW: 22201 23rd Dr. SE., Bothell, WA 98021-4421.

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

Subpart D [Reserved]

Subpart E—Criminal Violations

AUTHORITY: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for